REMARKS

In the Office Action mailed December 5, 2002, the Examiner rejected claims 1-20 as being anticipated by U.S. Patent 6,083,207 to Heck ("the '207 patent") under 35 U.S.C.§102(e). As discussed below, the claims are believed patentable over the art of record and this rejection is respectfully traversed. Reconsideration of claims 1-20 is respectfully requested.

Aspects of the instant invention are related to an epidural needle that permits the caregiver to selectively control the movement of a spinal needle with respect to an epidural needle. Specifically, as set forth in the independent claims, the epidural needle includes an elongate tube attached to a hub. A hollow bore in the tube is aligned with an open passageway in the hub. The hub includes a cavity disposed between its proximal and distal ends. A resilient member is provided is disposed in that cavity. A clamp is provided that can be moved from an open position, in which the resilient member is unaffected, and a clamp position, in which strain on the resilient member reduces the inner diameter of the opening through the resilient member. Claim 10 further recites a spinal needle, freely axially moveable within the hollow bore of the tube, that is fixed with respect to the epidural needle when the inner diameter of the resilient member is reduced. In use, the spinal needle can be displaced freely within the epidural needle when the clamp is in the open position. At the election of the caregiver, the clamp can be moved into the closed position, in which the spinal needle is fixed with respect to the epidural needle. The securement of the

needles is achieved without having to attach a separate structure during use. Rather, the hub, resilient member and clamp are always in place, allowing the caregiver to effect locking by merely sliding the clamp and release the lock by sliding the clamp back.

In contrast, the '207 patent is related to a partitioned hemostasis valve system. Specifically, a housing 12 has a generally clothspin-shape. Valve sections 38, 40 are disposed in each half of the housing. A spring 78 urges housing to a closed condition. In use, a medical device, such as a pacemaker lead, is advanced through a splittable sheath, which is already disposed in a patient's vein. The hemostasis valve system is then attached around the handle of the splittable sheath and over the device or lead. A split gasket 112, 113 of the hemostasis valve system forms a tight seal around the handle, preventing blood leakage. The valve sections 38, 40 are placed together and act like a conventional hemostasis valve. After use, the hemostasis valve system can be opened by forcing the wings together, and thereby open the housing. The hemostasis valve system can then be reused or thrown away. This operation is described at col. 9, lines 10-52 of the '207 patent. It is noted that the system is designed to permit sliding of the medical device through the valve when closed.

The Examiner indicates that the splittable valve housing 12 of the '207 patent corresponds to the tube of claim 1, that the valve section 38 corresponds to the hub, the catheter or medical device corresponds to resilient member; and that wings 70, 71 and lip 56 correspond to the clamp. It is unclear how the

housing could be a tube, how the valve could serve as a hub or how wings and a lip serve to clamp. Even assuming this to be the case, applicant's attorney respectfully asserts that the claims of the instant application cannot be construed to read on the structure of the '207 patent.

For example, Claim 1 requires that the hollow bore is in fluid communication with the passageway of the hub. In the '207 patent, the central chamber 13 does not appear to be in fluid communication with the sealing chamber 54 of the valve sections. Indeed, such communication might lead to undesirable fluid leakage.

The Examiner asserts that the catheter or medical device of the '207 patent serves as the resilient member. It is noted that the '207 primarily discloses using a lead for a pacemaker as the medical device that would be situated within the valve sections 38 and 40 when they are assembled. Such electronic leads are not understood to be resillent or to have an opening that can be subjected to strain. Further, there is no discussion of the catheter of the '207 patent being resilient or having an opening that can be reduced in diameter when subjected to strain. It is noted that the '207 patent expressly points out that the force exerted by the assembled valve sections is to be minimal, preventing fluid flow but not restricting movement of the medical device or catheter. See, e.g., the '207 patent, col. 6, lines 42-46. Consequently, there is no teaching that the valve sections exert a force to deform the catheter or pacemaker lead.

More fundamentally, the differences between the structure of the instant claims and the '207 patent arise from the very different nature of the devices themselves. The '207 patent relates to a split hemostasis valve that opens like a clothspin to attach onto splittable sheath to prevent blood flow while allowing advancement of a medical device, such as a pacemaker lead, therethrough. When applied, the hemostasis valve has a single condition, locking onto the splittable sheath, with the valve sections combined in a fixed position. As such, a medical device disposed within the valve sections would be subject to a constant force when the valve is in place. Conversely, the instant application is directed to a structure on an epidural needle including a clamp that can be moved from an open condition, which permits passage of the spinal needle, to a closed condition, straining a resilient member such that its inner diameter is reduced and binding on the spinal needle. This is simply not taught or suggested by the '207 patent.

Claims 3 and 12 recite that the portion of the clamp that projects outwardly from the hub includes a releasable latch. The Examiner cites elements 70 and 71 as the clamp and element 102 as the latch. However, as disclosed in the '207 patent, the latch 102 is not a part of wings 70 or 71. Rather, they are on opposite sides of the housing. Consequently, the wings could hardly be considered as including latch 102, as proposed by the Examiner.

Claims 7 and 16 recite that the clamp has a pair of legs and a radiused portion. The radiused portion is depicted, *inter alia*, as element 37a in Fig. 8.

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Claims 8 and 17 recite that the radiused portion of the pair of legs has the same radius as the radiused portion of the resilient member. The Examiner asserts that the wings 70 and 71 have a radiused portion at the proximal end. It is unclear to what structure the Examiner is referring. Further, there is no teaching or suggestion that the wings have a radius that is the same as the radius of the medical device or catheter. The Examiner has asserted that these radii are considered to be the same but has pointed out no portion of the '207 from which this can be discerned.

Regarding claims 9 and 18, the Examiner has not pointed out where a second radiused portion is depicted in the '207 patent, other than as somewhere on wings 70 and 71. Applicant's attorney is simply unable to understand what structure of wings 70 and 71 can meet this structural imitation.

Claim 10 requires a spinal needle. The Examiner purports that this structural limitation is met by the discussion in the '207 patent of a catheter or other medical device. Applicant's attorney respectfully asserts that a spinal needle is a specific structure that cannot be fairly met by identifying some "medical device." Specifically, a catheter and pacemaker lead is quite different from a spinal needle. Further, there is no disclosure in the '207 patent to grasp the spinal needle to fix its position with respect to the epidural needle. Indeed, the '207 patent teaches away from such a structure. See, col. 6, lines 42-46.

Referring to claim 11, the indicia formed on the needle is depicted as element 13. As can be understood, the indicia is along the spinal needle.

Examiner has asserted that spinal needles are considered to have such structures because a caregiver could look to the movement of the proximal end of the spinal needle. While a caregiver could do so, that is not what is being claimed. The indicia recited in this claim is along the spinal needle and permits the caregiver to know how far the spinal needle has been advanced without looking away from the insertion point.

Regarding claim 19, the Examiner has asserted that the resilient member of the '207 patent, which is the catheter or medical device is deformed. There is simply not disclosure of such a feature. Indeed, the nature of the valve of the '207 patent (which permits advancement of the medical device) argues that anything passing through the valve should not be deformed (because that may result in a resistive force which is too high to be operable).

Regarding claim 20, the wings 70, 71, latch 102, 104 do not form a U-shaped member, but rather an X-shaped member with a central pivot. There is no living hinge at all. The latch 102, 104 is not on the wings 70, 71. It is not understood how this structure could be construed to anticipate claim 20.

Conclusion

The claims of the instant application are believed patentable over the art of record and prompt, favorable action is respectfully requested. Should any issues remain outstanding, the Examiner is invited to call the undersigned.

Respectfully submitted,

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